REMARKS

Claims 24 and 25 have been cancelled without prejudice in order to reduce the issues. Accordingly, no new matter has been added.

Claims 7-22, 24 and 25 are rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

In support of the rejection, the Examiner states "[n]ovel biological molecules lack well established utility and must undergo extensive experimentation." Initially, in response, Applicants are unaware of any basis in the law for the Examiner's statement. Accordingly, respectfully submitted, such is believed to be plainly immaterial to the inquiry under 35 U.S.C. §101.

In any event, however, Applicants wish to point out that the present invention does satisfy 35 U.S.C. §101. To violate 101, the claims "must be totally incapable of achieving a useful result." Brooktree Corp. v. Advanced Micro Devices, Inc., 24 USPQ 2d 1401, 1412 (Fed. Cir. 1992). In this regard, the Patent Office issued Revised Interim Utility Guidelines at 64 Fed. Reg. 71440-42 on December 21, 1999. According to the Revised Guidelines, a single credible assertion of specific and substantial utility for any claimed invention satisfies the utility requirement. Id at 71441. The Revised Guidelines

According to the Revised Guidelines, the Examiner must establish a *prima facie* showing that is more likely than not one skilled in the art would not consider credible any specific and substantial utility asserted by Applicant. Id at 71442. The *prima facie* showing must contain the following elements:

1. An explanation that clearly sets forth the reasoning used;

2. Support for the factual findings relied upon in reaching this conclusion; and

3. An evaluation of all relevant evidence of record.

The Revised Guidelines emphasize the importance of documentary evidence establishing one of ordinary skill would disbelieve any utility described in the specification for the invention. A *prima facie* showing should provide scientific or technical journals, excerpts from treatices or books, or U.S. or foreign patents to support the factual basis. Id.

There was no such documentary evidence provided by the Examiner in support for her factual findings. Accordingly, there is no adequate basis for the rejection under Section 101. In any event, it is also clear Applicants do meet their burden of showing a credible, specific and substantial utility.

The nucleotide is a full-length clone that encodes a secreted or transmembrane protein isolated from human stomach cancer. Specification (PCT JP98 04475), page 10, Table 1. As the Examiner recognized, Applicants believe the protein has sequences which are sufficiently similar to stem cell antigen 2 and AA476643 that those of ordinary skill expect it to share activity with those peptides.

specific prior art proteins and have set forth their belief that the present invention would

share at least a part of their activities. For that reason alone the present invention plainly satisfies 35 U.S.C. §101.

However, the present invention is also useful, at least, as a research tool for better characterizing the activities of the prior art stem cell antigen 2 and AA476643 peptides.[1] Plainly, this itself is a substantial and unique utility that is by no means generic to all nucleotide or peptide sequences. The Examiner has made nothing documentary of record evidencing the contrary, and the "support for the factual findings relied upon in reaching [her] conclusion" do not address all of Applicants assertions, as required by the Revised Guidelines.

Claims 7-22, 24 and 25 are also rejected under 35 U.S.C. §112 first paragraph. In support of this rejection, the Examiner states that because the invention is not supported by a substantial asserted utility, one of ordinary skill would not know how to use it. However, as seen explained above, the present invention is supported by a specific and substantial utility.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 7-22 remain presented for continued prosecution.

[1] It is noted for the record that Applicant's have added claims 24 and 25 drawn to a pharmaceutical composition and medical treatment, respectively.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

Attorney for Applicants
Lawrence S. Perry
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200